



A BAUSCH & LOMB Company

Original 510(k)
Replace TPS Coated Implants

K962844 33

Section 6

OCT 18 1996

510(k) Summary

Manufacturer Information:

Submitter's Name: Steri-Oss Inc.
Address: 22895 Eastpark Drive
Yorba Linda, CA 92887
U.S.A.
Contact's Name: Paul Gasser
Regulatory Affairs Specialist
Phone: 714-282-4800
Date Prepared: July 1996

Device Names:

Common Name: Implant
Trade Name: Replace TPS Coated Implants
Classification Name: Endosseous implant

Predicate Device:

Substantial equivalence is claimed to Nobelpharma's 3.75 mm implant.

Device Description:

How device functions: The Steri-Oss implant is designed to serve as support for prosthetic devices to restore patient chewing function.

Device Description (cont.):

Scientific concepts: Natural dentition is composed of a root (subgingival) and a crown (supragingival). Designs in existence are intended to mimic this structure to aid the patient in restoring natural masticatory function. The implant is designed to serve as the root of the artificial tooth and the abutment/prosthetic is designed to serve as the crown.

Characteristics: The implants are 3.8, 5.0 or 6.0 mm in diameter, from 8 - 18 mm in length and are composed of a titanium body and titanium coating. They are tapered, have a hexed superior surface, and are threaded.

Intended Use:

The implant is indicated for use in restoring masticatory function in the edentulous and/or partially edentulous patient.

Comparison to Predicate:

The following table provides a comparison of the technological characteristic of the Steri-Oss implant to the predicate.

Item	Predicate	Steri-Oss
Material	Titanium	Titanium
Diameter (mm)	3.75	3.8, 5.0, 6.0
Length (mm)	7 - 20	8 - 18
Geometry	Threaded	Same
Sterility	Sterile	Same

Performance Data:

A mathematical justification demonstrates the substantial equivalence of the predicate to the Steri-Oss products.